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09/673,710	03/07/2001	Sylvia Burssens	2364/100	3986

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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/673,710	Applicant(s) BURSSENS ET AL.
	Examiner Cynthia Collins	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-12 and 17-31, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that there is one single inventive concept that describes the unique special technical feature of each of Groups I-V, the finding that plants tolerant to abiotic stress may be obtained by introducing into a plant a sequence which results in the presence of a CDK protein that is not susceptible to inhibitory phosphorylation under abiotic stress conditions, which Hemerly et al. do not teach. This is not found persuasive because claim 1, which links Groups I-V, does not require that plants tolerant to abiotic stress be obtained. Furthermore, Hemerly et al. teach introducing into a plant a sequence which results in the presence of a CDK protein that is not susceptible to inhibitory phosphorylation. Since the claimed method does not require more than is taught by Hemerly et al., Groups I-V are not linked by a special technical feature as defined by PCT Rule 13.2, because introducing into a plant a sequence which results in the presence of a CDK protein that is not susceptible to inhibitory phosphorylation does not define a contribution over the prior art. Accordingly, claims 13-17 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed March 9, 2001, paper no. 7, is attached to the instant Office action.

Priority

Certified copies of PCT/EP99/02696 and EP 98201279.1 have not been received in this National Stage application.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Claim 24 is objected to because of the following informalities: "grape" is repeated twice. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 17-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for obtaining plants tolerant to abiotic stress conditions wherein the methods require the introduction of any nucleic acid molecule or regulatory sequence that results in the presence of a CDK protein that is not susceptible to inhibitory phosphorylation under abiotic stress conditions, including sequences that encode or affect a variety of CDK proteins, including PSTAIR type CDK proteins, CDC2a proteins, *Arabidopsis* CDK proteins, *Arabidopsis* CDK proteins which are free of phosphate at the tyrosine at a position that corresponds to position 15 in *Arabidopsis* CDC2a, *Arabidopsis* CDK proteins which are free of phosphate at both the tyrosine at a position that corresponds to position 15 in *Arabidopsis* CDC2a and the threonine at a position that corresponds to position 14 in *Arabidopsis* CDC2a, CDK proteins that are nonphosphorylatable CDK muteins, CDK proteins that are nonphosphorylatable CDK muteins wherein the tyrosine at position 15 is substituted to a nonphosphorylatable amino acid residue, CDK proteins that are nonphosphorylatable CDK muteins wherein both the tyrosine at position 15 and the amino acid at position 14 are substituted to a nonphosphorylatable amino acid residue, CDK proteins that are nonphosphorylatable CDK muteins wherein the tyrosine at position 15 is substituted to phenylalanine, and CDK proteins that are nonphosphorylatable CDK muteins wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine.

In contrast, the specification describes and characterizes only one nucleic acid molecule whose introduction into a plant results in plants that are tolerant to abiotic stress, a nucleic acid molecule that encodes an *Arabidopsis* CDC2a protein wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine (pages 37-41). While the specification mentions other sequences that might meet the structural limitations

of the claims, the specification does not describe or characterize any other nucleic acid molecule or regulatory sequence whose introduction into a plant results in plants that are tolerant to abiotic stress.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-12 and 17-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for obtaining plants tolerant to salt stress conditions, said method comprising introducing into a plant cell, plant tissue or plant a nucleic acid sequence encoding an *Arabidopsis* CDC2a protein wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine, does not reasonably provide enablement for method comprising introducing into a plant cell, plant tissue or plant other nucleic acid sequences encoding other amino acid sequences, or for methods for obtaining plants tolerant to other environmental stresses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method for obtaining plants tolerant to abiotic stress conditions wherein the methods require the introduction of any nucleic acid molecule or regulatory sequence that results in the presence of a CDK protein that is not susceptible to inhibitory phosphorylation under abiotic stress conditions, including sequences that encode or affect a variety of CDK proteins, including PSTAIR type CDK proteins, CDC2a proteins, *Arabidopsis* CDK proteins, *Arabidopsis* CDK proteins which are free of phosphate at the tyrosine at a position that corresponds to position 15 in *Arabidopsis* CDC2a, *Arabidopsis* CDK proteins which are free of phosphate at both the tyrosine at a position that corresponds to position 15 in *Arabidopsis* CDC2a and the threonine at a position that corresponds to position 14 in *Arabidopsis* CDC2a, CDK proteins that are nonphosphorylatable CDK muteins, CDK proteins that are nonphosphorylatable CDK muteins wherein the tyrosine at position 15 is substituted to a nonphosphorylatable amino acid residue, CDK proteins that are nonphosphorylatable CDK

muteins wherein both the tyrosine at position 15 and the amino acid at position 14 are substituted to a nonphosphorylatable amino acid residue, CDK proteins that are nonphosphorylatable CDK muteins wherein the tyrosine at position 15 is substituted to phenylalanine, and CDK proteins that are nonphosphorylatable CDK muteins wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine. The claims are also drawn to a vector and a transgenic plant cell or plant, including a transgenic plant which displays increased tolerance to abiotic stress and an additional phenotypic characteristic.

The specification discloses only one method for obtaining plants tolerant to only one abiotic stress condition (salt), said method comprising introducing into a *Arabidopsis* plants only one type of nucleic acid molecule, a nucleic acid sequence encoding an *Arabidopsis* CDC2a protein wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine, said nucleic acid sequence being operably linked to a CaMV 35S promoter (pages 37-41). The construct utilized is said to correspond to the construct taught by Hemerly et al. (EMBO J. 14 (1995), 3925-3936) (page 37 lines 5-7). The transgenic plants were show to be tolerant to salt stress (Figures 1 and 2). The specification does not disclose any method for obtaining plants tolerant to other environmental stresses, and the specification does not disclose any other nucleic acid molecule or regulatory sequences whose introduction into a plant results in plants that are tolerant to abiotic stress.

Guidance for making and using the claimed invention is necessary for enablement because it is unpredictable whether expression in a transgenic plant of any nucleic acid molecule or regulatory sequence that results in the presence of a CDK protein that is not susceptible to inhibitory phosphorylation under abiotic stress conditions will result in plants that are tolerant to

abiotic stress. It would require undue experimentation to determine which of the many unspecified and non-exemplified nucleic acid molecules or regulatory sequences to express such that a CDK protein that is not susceptible to inhibitory phosphorylation under abiotic stress conditions is present and present in sufficient quantity to result in the production of plants that are tolerant to abiotic stress. The function of each unspecified and nonexemplified protein could be positively or negatively affected by the amount of protein expressed and the presence and amount of other factors that might be required to activate or inhibit the protein's function. For example, Rathinasabapathi et al. teach the transformation of tobacco plants with nucleic acids that express spinach or beet betaine aldehyde dehydrogenase for the purpose of conferring stress tolerance (Planta, 1994, Vol. 193, pages 155-162). Rathinasabapathi et al. teach that the expression of a betaine aldehyde dehydrogenase transgene is only a first step toward engineering betaine biosynthesis in tobacco, because tobacco also lacks the preceding biosynthetic enzyme, choline monoooxygenase (page 156, column 1, first full paragraph). Rathinasabapathi et al. also teach that they chose to first obtain plants expressing the betaine aldehyde dehydrogenase transgene because the betaine aldehyde product produced by choline monoooxygenase is toxic to plants (*id.*).

Guidance for making and using the claimed invention is also necessary for enablement because the ability of a nucleic acid molecule or regulatory sequence to affect more than one type of abiotic stress is also unpredictable. Whether a protein involved in stress tolerance can affect more than one type of abiotic stress depends on whether or not that protein functions in a pathway common to multiple abiotic stresses. For example, Liu et al. teach that two transcription factors, DREB1 and DREB2, function in two separate signal transduction pathways under low

temperature and dehydration conditions respectively (The Plant Cell, 1998, Vol. 10, pages 1391-1406). The expression of DREB1 transcription factors is induced by low-temperature stress, whereas the expression of DREB2 transcription factors is induced by dehydration and high-salt stress (page 1398 Figure 6). Furthermore, overexpression of DREB1 in transgenic plants induced the expression of rd29A, a gene whose expression is induced by dehydration, high salt and low temperature stress in nontransgenic wild type plants, whereas overexpression of DREB2 did not induce rd29A expression (page 1402 Figure 11). Liu et al.'s observations indicate that plants respond to stress through independent as well as overlapping biochemical pathways. Accordingly, the ability of a protein to affect more than one type of abiotic stress would depend on whether that protein functions as part of an independent stress pathway or as part of an overlapping stress pathway.

Additionally, guidance for making and using the claimed invention is necessary for enablement because it would require undue experimentation to determine how to modify a CDK protein such that it is not susceptible to inhibitory phosphorylation under abiotic stress conditions and such that expression of the protein results in tolerance to abiotic stress. While the specification indicates that expression of an *Arabidopsis* CDC2a protein wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine results in the production of transgenic plants that are tolerant to salt stress, the specification does not provide sufficient guidance with respect to which amino acids to alter in other CDK proteins, and what specific substitutions to make, such that the resultant protein is not susceptible to inhibitory phosphorylation under abiotic stress conditions and such that expression of the protein results in tolerance to abiotic stress. Joubes et al. teach that cyclin-

dependent kinases form a conserved superfamily of eukaryotic serine-threonine kinases that have been identified in yeast, animals and plants, and that as of publication a total of 46 putative plant CDK proteins had been described in 23 species of algae, gymnosperms and angiosperms (Plant Molecular Biology, 2000, Vol. 43, pages 607-620, see abstract, page 610 column 1, page 610 column 2 first paragraph, page 613 Figure 2, for example). Given the large number of diverse CDKs known from plants as well as fungi and animals, making changes to any CDK to make it unsusceptible to inhibitory phosphorylation under abiotic stress conditions and able to confer tolerance to abiotic stress when expressed in a transgenic plant would be unpredictable.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the many unspecified and non-exemplified nucleic acid molecules or regulatory sequences to express such that a CDK protein that is not susceptible to inhibitory phosphorylation under abiotic stress conditions is present and present in sufficient quantity to result in the production of plants that are tolerant to abiotic stress, to determine which of the many unspecified and non-exemplified nucleic acid molecules or regulatory sequences to express to affect more than one type of abiotic stress, and to determine how to modify a CDK protein such that it is not susceptible to inhibitory phosphorylation under abiotic stress conditions and such that expression of the protein results in tolerance to abiotic stress.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, 5, 6, 10, 11, 18, 25, 26, 27, 29 and 30, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 20 and 29 are indefinite in the recitation of "abiotic stress". It is unclear what types of conditions are encompassed by the claims, as virtually any nonliving component of the environment could be construed as an abiotic stress to a plant.

Claim 1 is indefinite in the recitation of "tolerant", as tolerant is a relative term lacking a comparative basis.

Claim 1 is indefinite in the recitation of "a nucleic acid molecule or regulatory sequence", because it is unclear in what way a "regulatory sequence" would differ from "a nucleic acid molecule".

Claim 2 is indefinite in the recitation of "PSTAIRE type". It is unclear what the acronym "PSTAIRE" signifies, as an acronym may have more than one meaning. It is also unclear what characteristics a CDK would need to possess in order to be a "PSTAIRE type" CDK.

Claims 3, 5 and 6 are indefinite in the recitation of "CDC2a". It is unclear what the acronym "CDC2a" signifies, as an acronym may have more than one meaning.

Claim 10 is indefinite in the recitation of "Y-15 → F-15". It is unclear what the acronym "Y-15 → F-15" signifies, as an acronym may have more than one meaning.

Claim 11 is indefinite in the recitation of "T-14 → A-14". It is unclear what the acronym "T-14 → A-14" signifies, as an acronym may have more than one meaning.

Claim 18 is indefinite in the recitation of "UTR". It is unclear what the acronym "UTR" signifies, as an acronym may have more than one meaning.

Claim 25 is indefinite in the recitation of "the nucleic acid molecule of claim 20", which lacks antecedent basis, as claim 20 is directed to a method.

Claim 26 is indefinite in the recitation of "at least one nucleic acid molecule of claim 20", which lacks antecedent basis, as claim 20 is directed to a method.

Claim 27 is indefinite in the recitation of "additional phenotypic characteristic". It is unclear what type(s) of characteristics would be encompassed by the claim, as virtually any plant characteristic that can be measured or observed is a phenotypic characteristic, and the claims from which claim 27 depends provide no indication of what the phenotypic characteristic might be.

Claim 29 is indefinite in the recitation of "preferably", because it is unclear why tolerance to osmotic stress would be preferred.

Claim 30 is indefinite in the recitation of "additional phenotypic characteristic". It is unclear what type(s) of characteristics would be encompassed by the claim, as virtually any plant characteristic that can be measured or observed is a phenotypic characteristic, and the claims from which claim 30 depends provide no indication of what the phenotypic characteristic might be or how it came to be displayed.

Claim Rejections - 35 USC § 101

Claim 31 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 31 is drawn to harvestable parts or propagation material of a plant of claim 28.

Claim 31, as written, does not sufficiently distinguish over harvestable parts or propagation material of plants as they exist naturally, because the claim does not particularly point out any non-naturally occurring products. Although the plant of claim 28 comprises plant cells comprising at least one nucleic acid molecule of claim 20, the claims do not require that all the cells of the plant of claim 28 or the harvestable parts or propagation material of claim 31 comprise an isolated nucleic acid molecule. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by indicating that the harvestable parts or propagation material comprise the isolated nucleic acid of the instant invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 17-19, 22-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hemerly et al. (The EMBO J., 1995, Vol. 14, No. 16, pages 3925-3936, Applicant's IDS).

The claims are drawn to a method for obtaining plants, including tobacco plants, tolerant to abiotic stress conditions, said method comprising introducing into a plant cell, plant tissue or plant a nucleic acid molecule or regulatory sequence that encodes a nonphosphorylatable

Arabidopsis CDC2a mutein comprising a Y-15 → F-15 mutation and a T-14→ A-14 mutation. The claims are also drawn to a transgenic plant cell comprising a nucleic acid molecule or regulatory sequence that encodes a nonphosphorylatable *Arabidopsis* CDC2a mutein comprising a Y-15 → F-15 mutation and a T-14→ A-14 mutation and further comprising a nucleic acid molecule that is capable of conferring to a transgenic plant an additional phenotypic characteristic.

Hemerly et al. teach a method comprising introducing into an *Arabidopsis* or tobacco plant cell a nucleic acid molecule that encodes a nonphosphorylatable *Arabidopsis* CDC2a mutein comprising a Y-15 → F-15 mutation and a T-14→ A-14 mutation operably linked to a constitutive CaMV 35S promoter, and transgenic plants comprising said nucleic acid molecule (page 3926 Figure 1; paragraph spanning pages 3926-3927; page 3927 Figure 3). The plants transformed with the same nucleic acid molecule as that claimed would have inherently been abiotic stress tolerant. The transgenic plants taught by Hemerly et al. also display an additional phenotype as a consequence of the introduction of a nucleic acid molecule as their plants because their plants were also transformed with a nucleic acid molecule encoding a selectable marker (page 3935 column 1 third full paragraph).

Remarks

No claim is allowed.

Claims 20-21, 25, 26 and 28-31 are deemed free of the prior art due to the failure of the prior art to teach or suggest a method for obtaining plants tolerant to abiotic stress conditions by introducing into a plant cell, plant tissue or plant a nucleic acid molecule or regulatory sequence

that encodes a nonphosphorylatable *Arabidopsis* CDC2a mutein comprising a Y-15 → F-15 mutation and a T-14→ A-14 mutation, said nucleic acid molecule or regulatory sequence being operably linked to a promoter that is inducible by osmotic stress.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 30, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638